K070428

510 (K) Summary

JUL 17 2007

5.1 Device Trade Name:	Medicom Self Sealing – Sterilization Pouch
5.2 Named and Address of Manufacturer:	A.R. Medicom Inc. 1200 55th Avenue, Lachine, Quebec H8T 3J8 Canada
Establishment Registration Number:	9680179
Contact Person:	Jason Ludivg Senior Quality & Regulatory Writer Tel: (514) 636-6262 x 2222 Fax: (514) 636-6267 E-mail: jludvig@medicom.ca
5.3 Device Classification Names:	1) sterilization wrap containers, trays, cassettes & accessories. 2) indicator, Physical/Chemical Sterilization Process
Classification/Panel:	Class II, §880.6850 & 880.2800
Classification Advisory Committee:	General Hospital
Product Code:	1) KCT 2) JOJ
Recognized Performance Standard	ISO 11140-1:2005 (JOJ)
5.4 Predicate Devices	Winner® Self Seal Sterilization pouch
510(k) Number	K051242

5.5 Intended Use

The self-sealing sterilization pouches are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121°C. The recommended EO sterilization cycle is 100 – 120 minutes at 50 °C with a relative humidity between 60 – 85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch maintains the enclosed devices sterile up until one year post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.

5.6 510(k) Statement

A 510(k) statement for the new device, as required by 21 CFR 93, is replaced with this 510(k) summary.

5.7 Proposed Labeling

A comparison with the predicate labeling confirms our claim of substantial equivalence with the predicate. A draft copy of the proposed and predicate device labeling may be found in Section 11.

5.8 Device Description

The pouches are manufactured from a medical grade paper that is thermally sealed to a laminated film on the left, right, and bottom of pouch. The fourth side has an adhesive strip that is used to seal the paper to the film prior to sterilization of the enclosed medical device. The pouches contain external indicators used to indicate the pouches were processed via steam or EO sterilization. See Section 7 for a detailed device description including shelf life, sterility achievement and compatibility with steam and EO sterilization processes.

5.9 Comparison Testing

Side by side testing was conducted on the The Medicom Self Sealing sterilization pouch and the Winner® Self Seal pouch to determine substantial equivalence. Sterilant Penetration, Drying Time, Aeration, Biocompatibility, Package Integrity,

Material Compatibility, Sterility Maintenance, and Chemical Indicator Efficacy (recognized standard ISO 11140-1:2005) were the parameters used to determine substantial equivalence and validate the safety and efficacy of the device. See sections 6 for the complete substantial equivalence comparison table.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2007

Mr. Jason Ludvig
Senior Quality and Regulatory Writer
A.R. Medicom, Incorporated
1200 55th Avenue
Lachine, Quebec
H8T 3J8
CANADA

Re: K070428
Trade/Device Name: Medicom Self Sealing Sterilization Pouch
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: June 19, 2007
Received: June 21, 2007

Dear Mr. Ludvig:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

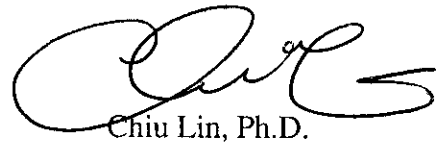
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K070428

Device Name: Medicom Self Sealing Sterilization Pouch

Indications For Use:

The self-sealing sterilization pouches are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121°C. The recommended EO sterilization cycle is 100 – 120 minutes at 50 °C with a relative humidity between 60 – 85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch maintains the enclosed devices sterile up until one year post sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.

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Prescription Use _____ **AND/OR** **Over-The Counter Use** **X**

(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila K Murphy MD

ivision Sign-Off)

ivision of Anesthesiology, General Hospital

nfection Control, Dental Devices

10(k) Number: K070428